

### ***Remarks***

Following the entry of the instant amendment, claims 4, 6, 9-11, 24, 26, and 35 to 48 are now pending in the application, with claims 4, 6 and 24 being the independent claims. Claim 5 has been cancelled. Claims 10 and 35 have been amended. The instant amendments do not introduce new matter.

Support for the amendments to claims 10 and 35, which introduce the term “heterologous” in front of “promoter” can be found in the specification from page 16, at line 25 to line 4 at page 17 of the disclosure as filed. This section of the Disclosure provides a definition of the term “heterologous” in the context of a heterologous control region, as further defined from lines 12 to 18, which defines “expression vector” (i.e., “the cloned gene (inserted sequence) is often placed under the control of control element sequences such as promoter sequence”, lines 14-16).

Applicants notes that “claims 4, 6, 9, 24, 26, and 37-48 are allowed” (page 5 of the Office Action).

The instant amendment is intended to overcome the new rejections following the withdrawal of the “indicated allowability of claims 5, 10, 11, 35 and 36”.

### ***Claim Objections***

The Examiner’s rejection of claim 5 as allegedly “being of improper dependent form for failing to further limit the subject matter of a previous claim” has been rendered moot by the cancellation of this claim.

Applicants emphasize that claim 5 has been cancelled to expedite prosecution and bring the instant claims in condition for allowance. Applicants retain the right to prosecute the cancelled or amended subject matter of the instant response in further applications.

For the record, Applicants respectfully disagrees with the allegation that “claim 5 as currently constructed is outside of the property boundary in claim 4”.

### ***Rejection Under 35 U.S.C. § 112, first paragraph***

The Examiner’s rejection of claims 10, 11, 35 and 36 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is respectfully

traversed. The Examiner states that the promoter encompasses the native PCA3 promoter.

Applicant respectfully submit that the recitation of the terminology “heterologous promoter” overcomes the Examiner’s rejection.

Currently amended claims 10, 11, 35 and 36 are fully enabled. At the time of the present invention, approximately 40 years following the description of the lambda promoter elements by Jacob and Monod (for which they obtained the Nobel prize), promoter elements for virtually all organisms were commonly known in the art. In fact, experiments such as subcloning of a desired piece of nucleic acid in an expression vector were being performed by high-school and college students. Excerpts from the reference in molecular biology, “Molecular Cloning” of Sambrook et al., 1989 (originally published in 1982, as Maniatis et al.) and cited at page 12, lines 11-12 of the application as filed, show that this classic laboratory manual contains about 20 pages relating to promoters with maps of expression vectors teaching how to introduce a desired piece of DNA therein (**Appendix 1**). Excerpt from a catalog of molecular biology products (dating from 1991) also shows how common expression vectors were (**Appendix 2**). Excerpts from a multitude of catalogs from different companies and numerous textbooks would also show how well known and common “heterologous promoters” were at the time of the present invention.

Accordingly, reconsideration and withdrawal of the rejection of claims 10 and 35 and of claims 11 and 36 dependent thereon, under 35 U.S.C. § 112, first paragraph, is respectfully requested.

### ***Rejections Under 35 U.S.C. § 102***

The Examiner’s rejection of claim 5 under 35 U.S.C. § 102(e), as being anticipated by US patents 6,465,611 and 6,395,278 has been rendered moot by the cancellation of claim 5.

Applicants nevertheless wish to stress that the subject matter of claim 4, on which claim 5 depends, must be considered in assessing novelty of claim 5. Claim 4 recites notably, the nucleic acid sequence of SEQ ID NO:1, and the fact that it is associated with a non-malignant prostatic state. None of these recitations are found in the 2 cited US patents. Thus, claim 5 should not be considered to be anticipated.

In any event, as discussed above, claim 5 was cancelled without prejudice or disclaimer to secure a quick allowance of this case.


***Conclusion***

Prompt and favorable consideration of this Amendment is respectfully requested. In view of the fact that claims 4, 6, 9, 24, 26, and 37-48 are already allowed, that rejected claim 5 was cancelled and that previously allowed claims 10-11 and 35-36 now overcome the rejection, Applicants urges the Examiner to allow the present application.

The Examiner is respectfully invited to telephone the undersigned at the number provided below to expedite allowance of this application.

Respectfully submitted,

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Encl. -Appendix 1  
-Appendix 2